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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,801	10/17/2003	Matthew S. Solar	723.077US1	9693

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EXAMINER	
KISH, JAMES M	
ART UNIT	**PAPER NUMBER**
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,801	SOLAR ET AL.	
	Examiner	Art Unit	
	James Kish	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Januray 30, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-21,23,24,31-35,40-48,50,51,58-63 and 65-68* is/are rejected.

7)☒ Claim(s) *11,22,25-30,36-39,49,52-57,64,69 and 70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/7/04, 10/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's election with traverse of claims 1-58 in the reply filed on January 30, 2007 is acknowledged. The traversal is on the ground(s) that a previous restriction (dated September 12, 2006) placed claims 1-70 in a single group and that the claimed subject matter of the newly restricted groups are not exclusive of one another. This has been found persuasive and therefore, the Restriction Requirement dated January 5, 2007, has been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-2, 5-6, 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 13-14 of copending Application No. 2004/0167393. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims relate to a fiducial marker comprising a head portion, a threaded shaft portion and a conical localization divot in the head portion using identical language.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, 8, 17, 59, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al. (US Patent No. 6,226,548). Foley discloses an apparatus and procedure for percutaneous placement of surgical implants and instruments such as screws, rods, wires and plates, into various body parts using image guided surgery (see Abstract). Figures 7 and 7A depict a screw that can appear within an imaging scan and also may contain a divot or other specially shaped interface on the head so that a pointer probe can be used to point to the head of the screw and indicate the orientation of the screw or wire to the surgical navigation system (column 9, line 44 through column

10, line 14). The screw can be attached to a device such as a bone clamp (column 6, lines 41-47). The fiducial array is composed of titanium or aluminum spheres and reference arcs include passive reflective spheres or other tracking means such as acoustic, magnetic, electromagnetic, etc. for indicating the location of the reference arc and, thus, the body part it is attached to, during medical procedures. Also see column 8, line 54 through column 9, line 13.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2, 6, 17 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Mittelstadt (US Patent No. 6,430,434). Mittelstadt discloses a marker structure comprising a fiducial marker pin. The bone marker has at least one barb for securing the bone marker into the bone. A conical locating feature is found at the top end of the marker. When a digitizer arm is brought into contact with conical locating feature, the exact position is determined (column 6, lines 15-42). When imaged from

above, the apex of the conical divot appears in the center of the marker. See Figure 1 for an illustrative description of the structure.

5. Claims 1, 3-4, 6-7, 12, 23-24, 59, 61, 63 and 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter et al. (US Patent No. 6,499,488). Hunter discloses an integrated anchor/localization sensor adapted to be secured to an anatomical structure. See Figure 1A and 1B. A female receptacle 29 is located in a faceted cylindrical housing that can be fixedly attached or integrated with the bone screw 18. The receptacle 29 engages with sensor 28, which has applicability in surgical procedures where it is desirable to track the relative movement of one or more structures. The housing comprises a disc-like base with an opening 27 and a circumferential cylindrical wall. Also, Figure 1B shows an unlabeled guide collar. See column 2, lines 35-40; column 4, lines 1-13; column 5, lines 55-62 and column 6, lines 10-13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-5, 9, 13-21, 32-35, 41-48, 59-61 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US Patent No. 5,397,329) in view of Vilsmeier

(US Patent No. 6,351,659). Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). However, Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be obvious to use one of these other screwdriver shapes. A trocar is placed at the anchoring site and the marker is placed within the trocar, thereby providing a guide collar about the marker (column 8, lines 1-9). Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column14, lines 28-53). While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by

a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). However, there is no means provided for locating the exact center with the localization system. Vilsmeier states that the funnel configuration allows the surgeon to access precisely the centerpoint of the landmark with the pointer (column 7, lines 20-47).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. in view of Zinreich et al. Foley discloses an apparatus and procedure for percutaneous placement of surgical implants and instruments such as screws, rods, wires and plates, into various body parts using image guided surgery (see Abstract). However is no discussion of a hydroscopic material. Zinreich discloses a multi-modality radiographic marker comprising a sponge-like matrix that retains a liquid used to provide contrast (column 36-54). It would be obvious to one having ordinary skill in the

art at the time the invention was made to incorporate a hydroscopic material in the head portion of Foley's device as one of many variations of reference arcs (see column 3, lines 22-27) to provide capability of imaging with different imaging modalities, as described at column 3, lines 29-50 (of Foley), in order to increase utility of the marker system.

8. Claims 23, 40 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier, further in view of Bulstra et al. (US Patent No. 6,102,914). Allen in combination with Vilsmeier is described in the above rejection of claims 1-5, 9, 13-16, 17-21, 32-35, 41-48, 59-61 and 67. However, neither reference clearly teaches a cap. Bulstra teaches a bone screw cap that shows X-ray visibility. Figure 1 A, 1B and 2 illustrate the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a cap to place on the head of the bone screw/fiducials of Allen/Vilsmeier in order to protect the hexagonal indentation used for insertion and removal of the screw.

9. Claims 31 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier, further in view of Franck et al. (US Patent No. 6,273,896). Allen in combination with Vilsmeier is described in the above rejection of claims 1-5, 9, 13-16, 17-21, 32-35, 41-48, 59-61 and 67. However, neither reference clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband to place them. It would have been obvious to one

having ordinary skill in the art at the time the invention was made to include a cap to place on the head of the bone screw/fiducials of Allen/Vilsmeier in order provide an alternative method of placing the markers that is less invasive for the patient.

Allowable Subject Matter

10. Claims 11, 22, 25-30, 36-39, 49, 52-57, 64, and 69-70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Other related art:

Franklin et al.	(see Figure 1B)	6,459,927 B1
Ahmad		2005/0043735 A1

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

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